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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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12/30/2004

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EXAMINER

CHORBAJI, MONZER R

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 12/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/879,117

Applicant(s)

WANSELIN ET AL.

Examiner

MONZER R CHORBAJI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 12/23/2004.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This final action is in response to the amendment received on 10/13/2004

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "3" and "3b" have both been used to designate back wall. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement-drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 6; applicant uses the term "a sterilization enclosure" as equivalent to "sterilization chamber". The use of the same term to refer to the same feature is needed to understand claim 1. Correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2, 5-6, 12-13, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Spence (U.S.P.N. 4,919,888).

With respect to claim 1, the Spence reference teaches a sterilization chamber (figure 1, 12 and 14 or 10) for use in a sterilization device (col.6, lines 18-21) such that the sterilization chamber encloses goods to be sterilized (col.6, lines 34-37) and has a self supported structure being essentially made of a polymeric material (col.4, lines 30-36). In addition, the chamber (10) is put into position (i.e., mounted) within the remaining sterilization device (col.6, lines 18-21) such that the chamber defines a portion of a sterilization enclosure (by being within the device) in the sterilization device. The sterilization chamber (10) includes an inlet integrally formed with the chamber (figure 1, 36. side walls act as integral steam inlets and outlets until the chamber is fully sealed) for connection to a sterilant source (steam within the device). The interior of the sterilization chamber (10) is intrinsically pressurized upon the entry of steam to within the chamber in order to sterilize goods to be sterilized.

With respect to claims 2, 5-6, 12-13, and 15, the Spence reference teaches the following: chamber is made of an injection-mouldable material that is essentially a polyamide material (col.4, lines 36-37 and col.4, line 31), chamber is made of a

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composite material (col.4, line 31), chamber is essentially manufactured in one continuous piece (col.4, lines 35-37), inlets and outlets for steam are integrally formed in the chamber (figure 1, 36. side walls act as integral steam inlets and outlets until the chamber is fully sealed), and a sterilization device being provided with a sterilization chamber intended for a sterilization process to be performed (col.6, lines 18-24).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 3-4, 7-9, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spence (U.S.P.N. 4,919,888) in view of Quehl (U.S.P.N. 4,165,404).

The teachings of the Spence reference have previously been set forth with regard to claims 1-2, 5-6, 12-13, and 15. With respect to claims 17-18, the Spence reference teaches that chamber is made of an injection-mouldable material that is essentially a polyamide material (col.4, lines 36-37 and col.4, line 31). However, with respect to claims 3-4, 7-9, and 16, the Spence reference fails to teach the following: the use of a reinforcement material such as rowing weave, and the use of carbon fiber and a concatenating polymer material such as an epoxy material. However, with regard to claims 3-4, 7-9, and 16, the Quehl reference teaches the following: the use of a reinforcement material such as rowing weave (col.2, lines 11-14 and line 45) arranged around the injection mouldable material (col.7, lines 24-27 and lines 48-50), and the use of carbon fiber (col.2, line 44) and a concatenating polymer material such as an epoxy material (col.6, lines 10-12), the use of glass fiber (col.2, line 44) and a concatenating polymer material (col.6, lines 10-12). Thus, it would have been obvious to one having ordinary skill in the art to modify the chamber of the Spence reference to include glass or carbon fibers because of their desirable physical properties as shown in the Quehl reference (col.2, lines 47-48).

9. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spence (U.S.P.N. 4,919,888) in view of Quehl (U.S.P.N. 4,165,404) and further in view of Limbacher et al (U.S.P.N. 5,837,181).

With respect to claim 10, both the Spence reference and the Quehl reference fail to teach the use of specific types of concatenating polymers provided in such a claim. However, the Limbacher reference teaches the use of polyvinyl alcohol fibers (col.5, lines 25-26). Thus, it would have been obvious to one having ordinary skill in the art to modify the sterilization chamber of the Spence reference to include polyvinyl alcohol since such a fiber is known to have a high modulus as taught by the Limbacher reference (col.5, lines 25-26).

10. Claims 11, 14, and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spence (U.S.P.N. 4,919,888) in view of Houston et al (U.S.P.N. 5,894,014).

With respect to claims 11, 14, and 19-20, the Spence reference fails to disclose that the chamber is releasably mountable in the sterilization device and the chamber is provided with a pair of integrally formed tracks, in which a sealing chamber door may be slidably mounted. However, the Houston reference teaches that the chamber (12) is releasably mountable (12 is fastened or secured to 28) in the sterilization device (10) and the chamber (12) is provided with a pair of integrally formed tracks (36), in which a sealing chamber door (30) may be slidably mounted (col.2, lines 62-65). Thus, it would have been obvious to one having ordinary skill in the art to modify the chamber of the Spence reference to include a pair of integrally formed tracks in order to provide for

vertical travel of the sealing chamber door as disclosed by the Houston reference (col.2, lines 64-65).

Response to Arguments

11. Applicant's arguments filed 10/13/2004 have been fully considered but they are not persuasive.

On page 7 of the Remarks section, applicant argues that, "Hence, unlike the container of system 10 of Spence, the sterilization chamber of the present invention is not dependent upon being placed within a portion of the sterilization device wherein the surrounding atmosphere defines the sterilization conditions, but rather, the sterilization chamber itself has an inlet for connection to a sterilant source." The instant amended claim 1 does not provide exclusion for placing the chamber within the device. As a matter of fact, instant dependent claims 11, 14 and 19-20 recite the feature of releasably mounting the chamber in the device. Such a limitation is addressed by using the Houston reference. See page 6 of the office action dated 07/13/2004.

On page 7 of the Remarks section, applicant argues that, "Thus, in contrast to Spence, the sterilization chamber of the present invention can be mounted in the sterilization device and to define the sterilization enclosure in the sterilization device." The chamber (10) of the Spence reference defines a space within which medical articles are sterilized. It is a chamber because it is a sealed enclosure (abstract, lines 1-8). The chamber is mounted within the sterilization device. The meaning of "mounted" has previously been explained on page 3 of the office action dated 07/13/2004.

Conclusion

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12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

13. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 6:30-3:00.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (571) 272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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